

**REMARKS/ARGUMENTS**

A certified copy of priority document PCT/EP 99/07417 is enclosed herewith.

An RCE is filed together with the present amendment.

An IDS filing under MPEP 609D with one item of information listed therein was attached to the Office Action dated January 14, 2002, and this item of information appeared lined through therein with a handwritten footnote reading “not a publication per se”. Applicants respectfully submit that an IDS filing is to report “information”, such as “patents, publications, U.S. applications, or other information”. (Underlining added) M.P.E.P. § 609 III.A(1), p. 600-120, 8<sup>th</sup> ed. (Aug. 2001). Accordingly, the European Search Report listed in the IDS filing referred to hereinabove, that was enclosed as such report in the same filing, should be considered by the US PTO and its entry into the record should be indicated by the initialization of the same item in the IDS filing.

A clean copy of the sheet Submission Under MPEP 609 D as previously submitted is attached to this Response. Applicants respectfully request its reconsideration. The Search Report itself is not enclosed herewith because it was part of the prior filing and it should therefore be part of the PTO records. The Examiner is respectfully requested to consider the referred item of information and initial the appropriate form for the record.

Claim 10 has been amended to clarify its language and the amended recitation does not narrow its scope. The amendment merely consists of the introduction of a preposition to place the language recited in the same claim in conventional syntactical form. No substantive changes have been introduced, and therefore support for this amendment is found in at least the same claim as pending before the present amendment.

The pending claims stand rejected under the nonstatutory double patenting doctrine in view of claims 1-4 of U.S. Pat. No. 6,197,779 (hereinafter the “779 patent”).

Applicants reassert in this regard the arguments and remarks set forth in the prior response dated May 14, 2002. Applicants respectfully submit the following additional arguments and remarks showing that: (1) The claims in the present Application do not recite the same subject matter as the claims in the '779 patent; (2) even if, *arguendo*, the present Application and the '779 patent claimed in part the same subject matter, the claims in the present Application have different scope than that of the claims in the '779 patent; (3) the claims in the present Application are not an obvious variation of the claims in the '779 patent; and (4) the claims in the present Application may not be rejected under the nonstatutory double patenting doctrine in view of claims 1-4 of the '779 patent.

(1) As set forth in the prior response dated May 14, 2002, the pending claims do not recite the same subject matter as the claims in the '779 patent because of at least the following reasons.

It follows from the comparison of the symbols in the pending claims and in the '779 patent that the Y-substituent in the pending claims corresponds to the R<sup>5</sup>-substituent in claims 1-4 of the '779 patent. A comparison of the recitations of the various possibilities for the Y-substituents and for the R<sup>5</sup>-substituents, for example, reveals that while the '779 patent recites that the R<sup>5</sup>-substituent is hydrogen or C<sub>1-4</sub> alkyl, the corresponding Y-moiety in the pending claims may be hydroxy, halo, C<sub>3-7</sub>cycloalkyl, C<sub>2-6</sub>alkenyl optionally substituted with one or more halogen atoms, C<sub>2-6</sub>alkynyl optionally substituted with one or more halogen atoms, C<sub>1-6</sub>alkyl substituted with cyano or -C(=O)R<sup>6</sup>, C<sub>1-6</sub>alkyloxy, C<sub>1-6</sub>alkyloxycarbonyl, carboxyl, cyano, nitro, amino, mono- or di(C<sub>1-6</sub>alkyl)amino, polyhalomethyl, polyhalomethyloxy, polyhalomethylthio, -S(=O)<sub>p</sub>R<sup>6</sup>, -NH-S(=O)<sub>p</sub>R<sup>6</sup>, -C(=O)R<sup>6</sup>, -NHC(=O)H, -C(=O)NHNH<sub>2</sub>, -NHC(=O)R<sup>6</sup>, -C(=NH)R<sup>6</sup> or aryl.

Serial No. 09/430,966

Neither "hydrogen" nor " $C_{1-4}$  alkyl" is recited as one of the Y-substituents in the pending claims. Furthermore, none of the Y-substituents recited in the pending claims is recited as an  $R^5$ -substituent in claims 1-4 of the '779 patent.

Because of the difference in recited subject matter, at least concerning  $R^5$  in the '779 patent and Y in the pending claims as shown hereinabove, claims 1-4 of the '779 patent and the pending claims recite different subject matter. The pending claims do not recite the same elements as the claims in the '779 patent, and the claims in the '779 patent do not recite the same elements as the pending claims.

(2) As set forth in the prior response dated May 14, 2002, the pending claims do not have the same scope as the claims in the '779 patent because of at least the following reasons.

For example, in claim 1 of the '779 patent, the L, Q and  $-NR^3$ -phenyl (or pyridyl) substituents float freely on the pyrimidine ring and each may be attached at any available position in such ring. By contrast, in the pending claims, all of the substituents (L, Y, Q and  $-NR^3$ -phenyl (or pyridyl)) are attached to the pyrimidine ring in fixed positions.

Even if, *arguendo*, this difference were the only difference between the pending claims and the claims in the '779 patent, Applicants note that a case that the pending claims are not patentably distinct from the claims in the '779 patent has not been established. Consequently, a double patenting rejection should not be asserted. *See, e.g., In re Sarett*, 327 F.2d 1005 (C.C.P.A. 1964) (reversing all the rejections by the US PTO Board of Patent Appeals and Interferences that had been predicated on nonstatutory double patenting, and holding that the claims in a pending patent application that specifically recited a "pyridine-chromium trioxide complex" as an oxidizing agent were patentably distinct from the claims in an issued patent that generically recited "an oxidizing agent").

Serial No. 09/430,966

(3) The claims in the present Application are not an obvious variation of the claims in the '779 patent. As shown above, the claims in the '779 patent recite different subject matter than that recited in the pending claims. Furthermore, there is no showing of record that the presently claimed subject matter could be obtained as an obvious variation of the —different— subject matter recited in the claims of the '779 patent.

Concerning the assertions in the first full paragraph in the Office Action, p. 3, Applicants respectfully note that at least the foregoing arguments show that the “equivalency teaching”, as alleged in the Office Action, is not satisfied with respect to the pending claims, and that there is no such “equivalency teaching”. Furthermore, and concerning the broad and generic reference made in the same paragraph of the Office Action to the disclosure in the '779 patent, Applicants respectfully note that

[o]ne significant difference [between a double patenting rejection and rejections based on prior art] is that a double patenting rejection must rely on a comparison with the claims in an issued or to be issued patent, whereas an obviousness rejection based on the same patent under 35 U.S.C. §§ 102(e)/103(a) relies on a comparison with what is disclosed (whether or not claimed) in the same issued or to be issued patent. In a 35 U.S.C. §§ 102(e)/103(a) rejection over a prior art patent, the reference patent is available for all that it fairly discloses to one of ordinary skill in the art, regardless of what is claimed. (Citation omitted).

M.P.E.P. § 804.III, p. 800-29, 8<sup>th</sup> ed. (Aug. 2001). The comparison of the pending claims with the claims in the '779 patent reveal that they recite different subject matter and that the pending claims are not obvious variations of the claims in the '779 patent.

(4) It has been established that “[o]bviousness-type double patenting entails a two-step analysis.” *Eli Lilly & Co. v. Barr Laboratories, Inc.*, 55 U.S.P.Q.2d 1609, 1617 (Fed. Cir. 2000).

First, the construed claims are overlaid “to determine whether the later claim encompasses subject matter previously claimed.” *Id.*, at 1617. *See also In re Sarett*, 327 F.2d 1005 (C.C.P.A. 1964) (stating with respect to the specifics of a double patenting

Serial No. 09/430,966

rejection that “the question is whether the ... invention [recited in the pending claims] is in effect claimed in the issued ... patent [used as a purported basis for a double patenting rejection]”, and reversing all the rejections that had been predicated on such ground). As shown herein, the pending claims do not recite subject matter that is recited in the claims of the ‘779 patent, and the claims in the ‘779 patent do not recite subject matter that is recited in the pending claims. Therefore, the answer to the first part of the inquiry on the appropriateness of an obviousness-type double patenting rejection is in the negative.

In the second step, it is to be determined “whether the differences in subject matter between the two claims [are] such that the claims are patentably distinct.” *Eli Lilly & Co. v. Barr Laboratories, Inc.*, 55 U.S.P.Q.2d 1609, at 1617. In this regard, “double patenting is not ‘concerned with what one skilled in the art would be aware [of] from reading the claims but with what inventions the claims define.’” (Preposition added in the original; quotation omitted). *Id.*, at 1618. As shown herein, the pending claims and the claims in the ‘779 patent recite different, non-overlapping, subject matter, and they define different inventions. The pending claims must therefore be regarded as patentably distinct from the claims in the ‘779 patent. Furthermore, no case has been made to show that the pending claims would not be patentably distinguishable from the claims in the ‘779 patent, particularly in light of the differences between the pending claims and the claims in the ‘779 patent.

For at least the foregoing reasons Applicants respectfully submit that the pending claims may not be rejected under the nonstatutory double patenting doctrine in view of claims 1-4 of the ‘779 patent, and consequently request the removal of these rejections.

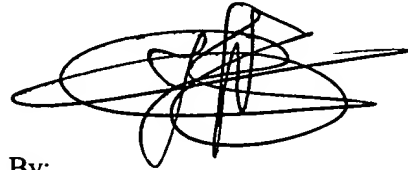
Attached hereto is a marked-up version of the changes made to the claims by the current amendment. The attached page(s) is/are captioned “Version with markings to show changes made”. As indicated in the foregoing remarks, a clean copy of the sheet Submission Under

Serial No. 09/430,966

MPEP 609 D as previously submitted is attached to this Response following the "Version with markings to show changes made".

Applicants respectfully request that a timely Notice of Allowance be issued in this case.

Respectfully submitted,

A handwritten signature in black ink, consisting of several overlapping loops and a long horizontal stroke extending to the right.

By: \_\_\_\_\_  
Jesús Juanós i Timoneda, PhD  
Reg. No. 43,332

Johnson & Johnson  
One Johnson & Johnson Plaza  
New Brunswick, NJ 08933-7003  
(732) 524-1513  
Dated: March 6, 2003

Serial No. 09/430,966

[INSTRUCTIONS: THIS SECTION IS WHERE YOU SHOW EACH CHANGE MADE IN THE SPEC & CLAIMS BY USING YOUR UNDERLINING AND STRIKETHROUGH MARKINGS ]

**VERSION WITH MARKINGS TO SHOW CHANGES MADE**

**In the Claims:**

10. (Thrice amended)            The method of Claim 8, wherein R<sup>1</sup> is hydrogen, aryl, formyl, C<sub>1-6</sub>alkylcarbonyl, C<sub>1-6</sub>alkyl, C<sub>1-6</sub>alkyloxycarbonyl, C<sub>1-6</sub>alkyl substituted with formyl, C<sub>1-6</sub>alkylcarbonyl, or C<sub>1-6</sub>alkyloxycarbonyl.